

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OKLAHOMA

STATE OF OKLAHOMA, *et al.*,)

Plaintiffs,)

v.)

Case No. 4:05-cv-00329-GKF-PJC

TYSON FOODS, INC., *et al.*,)

Defendants.)

**DEFENDANTS' REPLY IN SUPPORT OF MOTION TO EXCLUDE THE
TESTIMONY OF DR. VALERIE J. HARWOOD PURSUANT TO
DAUBERT v. MERRELL PHARMACEUTICALS, INC. (Dkt. No. 2030)**

Defendants respectfully submit this reply brief in support of their motion to exclude the testimony of Plaintiffs' expert witness Dr. Valerie Harwood. *See* Dkt. No. 2030 ("Motion" or "Mot."). Plaintiffs' brief in opposition, *see* Dkt. No. 2115 ("Opposition" or "Opp."), is a creative yet unavailing *post hoc* effort to salvage Dr. Harwood's testimony. The Opposition incorporates some 125 pages of new expert declarations and reports, including a 28 page declaration from Dr. Harwood that substantially revises portions of her testimony.¹ Plaintiffs offer testimony from previously undisclosed experts putting forward new analyses based on samples collected and tests run long after the deadline for expert disclosures.² Plaintiffs propose a novel and untenable version of "peer review" by a party's own consultants. And, Plaintiffs attempt to downplay Dr. Harwood's reliance on her own biomarker methodology. But despite Plaintiffs' many contortions, it remains the case that Dr. Harwood's novel method has never survived review by

¹ Plaintiffs repeatedly incorporate these declarations by reference but without elaboration. The Tenth Circuit frowns upon this briefing tactic, which simply "allows litigants to circumvent page limitations and complicates the judges' responsibilities." *United States v. Heijnen*, 215 Fed. Appx. 725, 727 (10th Cir. 2007); *see Gaines-Tabb v. ICI Explosives, USA, Inc.*, 160 F.3d 613, 623-624 (10th Cir. 1998) (citing multiple authorities rejecting incorporation by reference). Plaintiffs' brief and substantive attachments total 144 pages. If the Court accepts these declarations, *see* n.2, *infra*, they merit consideration only to the extent that they are discussed substantively in Plaintiffs' brief.

² Each of Plaintiffs' declarations offers new analysis based on work performed after the deadline for expert reports in violation of Rule 26 and this Court's scheduling orders, and should therefore be excluded. *See Dura Auto. Sys. v. CTS Corp.*, 285 F.3d 609 (7th Cir. 2002) (striking affidavits from previously undisclosed experts offered in support of *Daubert* briefing); *Palmer v. ASARCO Inc.*, 2007 WL 2254343 (N.D. Okla. Aug. 3, 2007) (same); *Honaker v. Innova, Inc.*, 2007 U.S. Dist. LEXIS 30222, at *6-7 (W.D. Ky. Apr. 23, 2007) (same). Dr. Harwood offers numerous previously undisclosed opinions. Opp. Ex. A at 4-18. Dr. Sadowsky presents an entirely new expert report. *See* Opp. Ex. D, attch. 1. Drs. Weidhaas, Macbeth, and Harwood rely on his work along with additional testing conducted long after Dr. Harwood's report was served. *See* Opp. Ex. C at 18-22 (Harwood); Opp. Ex. F. at 8-13 (Macbeth); Ex. G at 5-8 (Weidhaas). Dr. Weidhaas and Dr. Macbeth offer undisclosed opinion and background testimony based on their own technical expertise. Opp. Ex. F. at 2-10 (Macbeth); Opp. Ex. G at 3-12 (Weidhaas). And Dr. Loftis offers statistical analysis to repair Dr. Harwood's failure to perform any, which relies in part on Plaintiffs' inappropriate post-report deadline testing. *See* Opp. Ex. H at 3, 6-7. Defendant will move separately to strike these declarations.

anyone outside of Plaintiffs' litigation team, and is fundamentally unsupported by the available data. Dr. Harwood's testimony should be excluded in its entirety under *Daubert*.

DISCUSSION

1. **Dr. Harwood's Biomarker Lacks Substantial Scientific Pedigree And Is Unsupported by the Data**

Plaintiffs *first* attempt to supply the biomarker's long-missing ancestry. They argue that PCR has been accepted in other courts, and should therefore be accepted in this one. *See Opp.* at 5. But this again conflates a methodology with the tools used to implement it. The authorities Plaintiffs cite simply recognize PCR as an appropriate method for duplicating and matching DNA. Defendants have never questioned that use; rather, Defendants dispute Plaintiffs' claim that the particular thing that Dr. Harwood's PCR primers replicate is unique to poultry litter. Dr. Harwood's method comprises the entire process supporting that claim, not just the PCR reaction. Plaintiffs similarly argue that Dr. Harwood's method should be accepted because it is a "library independent PCR method," which, they argue, are widely accepted.³ Again, Defendants have never disputed that some such methods exist, but the fact that Dr. Harwood has proposed and begun testing such a method does not make it reliable. Indeed, automobiles are a generally accepted form of transportation, but the Pinto has mercifully gone by the boards. The question is whether Plaintiffs' particular library independent method is reliable.

Contrary to their own prior admissions, *Mot.* at 7-9, Plaintiffs' consultants now claim that the biomarker follows a decade's worth of scientific research. *Opp.* at 7 (citing Harwood, Macbeth, and Weidhaas declarations).⁴ Specifically, Plaintiffs rely on research by Professor

³ Plaintiffs reference here to "PCR methods" in the plural undercuts their claim that PCR itself constitutes a single methodology. *Opp.* at 7.

⁴ Dr. Harwood previously took credit for leading this effort and is Plaintiffs' sole disclosed expert on these points. But Plaintiffs now rely principally on the work of Drs Macbeth and Weidhaas

Kate Field of Oregon State University. Opp. Ex. C ¶27; Opp. Ex. F. ¶10. But Professor Field's work is a microcosm of why Plaintiffs' claims are unreliable. She proposed a species-specific marker for cattle. *See Bernhard & Field, A PCR Assay to Discriminate Human and Ruminant Feces on the Basis of Host Differences in Bacteroides-Prevotella Genes Encoding 16S RNA*, 66 Jnl. of Applied & Enviro. Microbiology 4571 (2000). Yet, after thousands of field tests over many years, it proved no more specific than for ruminants generally. *See Shanks, et al., Basin-Wide Analysis of the Dynamics of Fecal Contamination and Fecal Source Pollution in Tilamook Bay, Oregon*, 72 Jnl. of Applied & Enviro. Microbiology 5537 (2006).⁵ The fact is that no other scientist has identified Plaintiffs' poultry specific biomarker, which, as she and her colleagues candidly admitted, remains entirely novel. Mot. at 7-8.

Second, Plaintiffs disclaim a need to test any additional animals before claiming that the biomarker is specific to poultry litter. Instead, they argue, it was appropriate to test only "the non-target fecal sources that are most likely to affect water quality." Opp. at 8. But this rationalization is entirely *post hoc*. Opp. Ex. C at 13. As Dr. Harwood admitted previously, Plaintiffs never attempted to analyze fecal contributions from other animals, and therefore had no basis to apply this late-minted criterion. Mot. at 17-18.⁶ Moreover, even if they had, the biomarker's ability to persist for long periods of time prevents the discounting of many less

who actually performed the work underlying Dr. Harwood's testimony. Mot. at 7-10. Such testimony should have been disclosed previously to allow Defendants a full opportunity to test their recollections and opinions as testifying experts. *See Dura*, 285 F.3d at 612-617.

⁵ Unlike Dr. Harwood, Dr. Field did perform statistical analyses, study watershed specific fate and transport issues, and examine multiple relevant correlations. *See id. generally*. Moreover, Dr. Field recognized that PCR is unreliable in that it replicates DNA from dead cells, and also that animal impacted waters pose less health risks than human-impacted. *Id.* at 5545.

⁶ Dr. Harwood's claim to have relied on Dr. Teaf's analysis thus contradicts her prior testimony. Opp. at 8. Moreover, Plaintiffs' reliance on undisclosed sample collection and testing performed after the expert report deadline should also be rejected. Opp. at 8-9.

populous species. *Id.* Therefore, Dr. Macbeth admitted that Plaintiffs' claim of host specificity cannot be expanded beyond the universe of tested animals. Mot. at 12. Plaintiffs' selection of control animals was arbitrary and insufficient.⁷

Third, Plaintiffs attack Dr. Myoda's testimony. Opp. at 9-10. However, Plaintiffs' claims of contamination and quality control failures are rank speculation. Indeed, IEH's labs are certified for the most rigorous analytical work by multiple professional associations and regulatory agencies. *See* Myoda Depo. at 53:5-9 (Ex. 1). Plaintiffs' claims that Dr. Myoda did not "duplicate the Biomarker protocols appropriately" and challenges to his conclusions are based on the selective and misleading presentation of materials at his deposition and a misunderstanding of his testimony. Moreover, Plaintiffs' objections contradict their own prior testimony. For example, Dr. Macbeth argues that Dr. Myoda did not identify the same biomarker organism in some of his samples because the identified DNA sequence was only 97 to 99 percent similar. Opp. Ex. F. ¶19. Yet, Dr. Harwood previously testified that in their field, bacteria with greater than 95 percent similarity are "indistinguishable." *See* Harwood July Dep. at 106:22-107:18 (Ex. 2). At any rate, Plaintiffs have not moved to exclude Dr. Myoda under *Daubert*, and are free to challenge him at trial where he will ably answer their allegations.⁸ For present purposes, Dr. Harwood's work is unreliable *regardless* of Dr. Myoda's findings.

2. Plaintiffs' Biomarker has not been Peer Reviewed

Having offered a piecemeal defense of Dr. Harwood's work, Plaintiffs next advance the remarkable claim that their biomarker methodology has been peer reviewed and validated by

⁷ Plaintiffs also cite Dr. Loftis's theory that tests of all non-poultry samples are appropriately considered collectively. This testimony is long tardy. Defendants challenged Dr. Harwood's statistical shortcomings at the preliminary injunction stage, *see* Mot. at 2, yet Plaintiffs neither had her perform this analysis, nor designated Dr. Loftis as an expert, *see* Mot. at 15-17.

⁸ Dr. Myoda's testimony is offered solely to rebut Dr. Harwood testimony. If Defendants' Motion to exclude Dr. Harwood is granted, Defendants will not call Dr. Myoda.

their own retained consultant, Dr. Mike Sadowsky. Opp. at 10-13. But Dr. Sadowsky's work is unpersuasive and irrelevant for several reasons. *First*, the declaration and report that Plaintiffs attach plainly constitute a new and undisclosed expert analysis, performed after the expert report deadline, *see* Opp. Exs. D, E, and as such are improper. *See Honaker v. Innova, Inc.*, 2007 U.S. Dist. LEXIS 30222, at **6-7 (W.D. Ky. Apr. 23, 2007) (rejecting effort to resuscitate an expert's testimony on *Daubert* with the late-disclosed testimony of another expert).

Second, while Plaintiffs strive mightily to broaden the definition of "peer review," Opp. at 10-12, even the most generous understanding does not include corroboration by a party's own consultant. Indeed, Courts have rejected the less extreme claim that review by opposing experts constitutes peer review. *See Honaker*, 2007 U.S. Dist. LEXIS 30222, at **4-5; *see also Gaskin v. Sharp Elec. Corp.*, 2007 U.S. Dist. LEXIS 65532, at *30 (N.D. Ind. Aug. 31, 2007) (rejecting as "untenable" plaintiffs' argument that review by opposing experts constituted "peer review."). The hallmark of "peer review" is *independent* review. *See* Mot. at 6-7; *see also United States v. Frabizio*, 445 F. Supp. 2d 152, 166 (D. Mass. 2006); *In re Breast Implant Litig.*, 11 F. Supp. 2d 1217, 1230-31 (D. Colo. 1998). Dr. Sadowsky's work is not independent review. Plaintiffs reimbursed him for his work, Opp. Ex. D ¶3, and while he claims to have worked without salary he makes no such representations regarding his colleagues, staff, or institution. Nor does he disclose his publication interests. *See* E-mail Correspondence at 3-4 (Ex. 3).

Third, Dr. Sadowsky's work is in any event irrelevant as he merely confirmed that Plaintiffs' primers replicate a given DNA sequence. *See* Opp. Ex. D. at 4-10. That claim is not in dispute; indeed, Dr. Myoda similarly confirmed that claim. *See* Mot. Ex. 14 at 27. But beyond that, Dr. Sadowsky did nothing to confirm Plaintiffs' claim that this DNA strand is

unique to poultry. He simply takes Plaintiffs' word for it. *See* Opp. Ex. D ¶11.b. His review therefore adds nothing to the parties' actual dispute.⁹

Of course, Drs. Harwood, Macbeth, and Weidhaas's work has been submitted to real, independent peer review by a leading journal, which rejected it. *See* Mot. *generally*. Plaintiffs downplay that rejection as routine and having "little to do with scientific reliability." Opp. at 13. Dr. Harwood, for her part, dismisses it on the basis that her first manuscript was "overly complex." Opp. Ex. C ¶41. But AEM did not merely decline to publish her manuscript for want of space, but rather soundly rejected it twice "for scientific reasons," because it was in part "inadequate," "inappropriate," and statistically unsupported. Mot. at 4-6.¹⁰ Dr. Harwood's work has been peer reviewed, and found wanting.

3. The Biomarker Method Has a Substantial But Unknown Error Rate

Plaintiffs next assert that the Biomarker has a known and measured error rate, which presumably supports its reliability. This claim rests entirely on inadmissible new opinions and is in any event highly misleading. At her first deposition, Dr. Harwood testified that an error rate for a library independent method must be established through blind comparison tests, but acknowledged that such tests have never been run. *See* Harwood Jan. Depo. at 240:20-241:19. (Ex. 4). At her second deposition she acknowledged having done no new analysis. *See* Mot. at

⁹ Interestingly, Dr. Sadowsky's report does reveal that he managed to replicate only 50 percent of Plaintiffs' test results on allegedly biomarker-positive environmental samples. *See* Opp. Ex. D ¶12. Such a gross variance is grounds for pause.

¹⁰ Plaintiffs also question the utility of peer review, arguing that "given the anonymity of the reviewers we cannot tell whether they had qualifications to judge the work represented by the paper." Opp. at 13. The Court can judge whether the scientists who wrote the pointed and technically detailed criticisms contained in AEM's peer review comments had any technical expertise in the field. *See* Mot. Exs. 1, 7. Moreover, Plaintiffs' disparagement of peer review here stands in stark contrast with the paean they sing to *confidential* peer review in their papers resisting discovery into their efforts to secure peer for their experts' work. *See* Plaintiffs' Motion for Protective Order, Dkt. No. 2034 (May 11, 2009) (seeking to avoid production of materials on the basis that it would violate the important confidentiality of the scientific peer review process).

4. Plaintiffs' new claim that the biomarker method has a known error rate depends entirely on tests performed after the expert report deadline by Plaintiffs undisclosed experts, Drs. Sadowsky, Macbeth, and Weidhaas. *See* Opp. at 13-14. These results should be put aside.

Plaintiffs' claim is moreover misleading as it overlooks the many uncertainties that characterize the development of the biomarker pointed out in Defendants' Motion, which substantially increase the method's error rate. *See* Mot. at 13 (Dr. Macbeth agrees that biomarker is "specific" only with regard to tested animals; BLAST database far from comprehensive); *id.* at 13-14 (use of various tools to manipulate melt curve results, introducing unknown error rates); *id.* at 15-16 (biomarker statistically unsupportable, especially given cluster sampling); *id.* at 17-19 (failure to test other relevant species undercuts claim to host specificity).

4. Plaintiffs Have Not Performed a Comprehensive Fate and Transport Analysis

Continuing to ignore their experts' many statements to the contrary, *see* Mot. at 11-12,¹¹ Plaintiffs again assert that they did conduct sufficient fate and transport analysis. Opp. at 14-15. To support this claim Plaintiffs simply refer the Court to their expert reports without specific citation or discussion. *See id.* at 14. These experts, they claim, demonstrate the presence of poultry litter at each stage of an alleged "pathway." *Id.* at 14-15. But Plaintiffs nowhere meet Defendants' principal objections, that Plaintiffs failed to account for the many alternate sources within the IRW of the same bacteria and chemicals that they claim demonstrate "poultry waste" at each stop along the alleged pathway, *see* Mot. at 10-12, 21-22, and failed to support their central assumption that these constituents move through the IRW in fixed proportions to each

¹¹ *See also* Brown Depo. at 194:6-95:3 (Plaintiffs did not take samples to follow alleged contaminants from specific edges of fields to surface waters) (Ex. 5); Fisher Depo. at 477:19-78:10 (no expert correlates land application to instances of contamination); *id.* at 549:1-19 (no field-by-field tracking analysis performed) (Ex. 5).

other, *see id.* at 19-21.¹² Plaintiffs' consultants now trumpet the importance of environment-specific fate and transport investigation. *See, e.g.*, Decl. of Rick Chappell, Dkt. No. 2072-6 (May 18, 2009) (criticizing Dr. Cowan for not having studied contaminant transport in the IRW). Yet, Professor Harwood undertook no such analysis of any bacterium in the IRW. *See Mot.* at 12. Indeed, the Tenth Circuit noted Plaintiffs' failure to perform any fate and transport study. *Attorney General of Oklahoma v. Tyson Foods*, 565 F.3d 769, 769 (10th Cir. 2009). Without some analysis of alternate sources and transport characteristics, constituents in the environment cannot be attributed to specific sources.

Plaintiffs claim that they did demonstrate a correlation between fecal indicator bacteria and *enterococci*. *See Mot.* at 19-21. Again, this misses the larger point. The problem is not only the suspect correlation, but the failure to study correlations anywhere other than in poultry litter. *See Mot.* at 19-21. Even assuming that Plaintiffs are correct that the biomarker and *enterococci* correlate in poultry litter, there is no proof that they maintain that correlation as they pass multiple other sources of each on their (alleged) journey to recreational waters in the IRW. Such a relationship cannot simply be assumed, and indeed, as Dr. Weidhaas recognized, is confounded by the existence of alternate sources of indicator bacteria. *See Mot.* at 22. Absent an analysis studying how the biomarker and other indicator bacteria move through the IRW, no valid conclusion can be drawn as to source from the presence of any of them.

5. Dr. Harwood's Testimony Regarding Human Health Risk Is Unreliable

¹² Contrary to Plaintiffs' claim, *Opp.* at 15, Defendants' authorities specifically note the need to account for alternate sources and study transport characteristics. *See Mot.* at 10-11 (citing authorities). Separately, Plaintiffs' assertion that phosphorous and bacteria move differently from synthetic pollutants, *Opp.* at 16, is irrelevant. Whatever the constituents, in order to conclude that the presence of one proves the source of another, the two must move together.

Finally, Plaintiffs attempt to save Dr. Harwood's more general health risk testimony by uncoupling it from her biomarker work. *See* Opp. at 17-18.

First, Plaintiffs argue that Dr. Harwood reached her health risk testimony independent from her work on the biomarker. Opp. at 17. In fact, they claim that she concluded that poultry litter causes health risks in the IRW even "*before* the memo written by the State's counsel that Defendants like to point to as evidence that the Biomarker was a creation of counsel." Opp. at 18. Given that the memorandum in question was written in September 2005, *see* Mot. Ex. 12, and that Dr. Harwood did not begin her substantive work on this case until Summer 2005 or form her conclusions until late 2007, *see* Mot. at 8-9, this claim is difficult to accept. Moreover, Plaintiffs' attempted decoupling contradicts Dr. Harwood's Rule 26 report, which states that

[t]he finding that a poultry-specific biomarker ... is found in all environmental compartments tested in the IRW ... firmly links a dominant portion of the indicator bacteria contamination to poultry waste, which is well known to contain important human pathogens such as *Salmonella* and *Campylobacter*. Thus, the disposal of poultry waste by land application in the IRW presents a substantial, serious and immediate threat to human health.

Mot. Ex. 3 at 23. Thus, far from some insubstantial sideshow, Dr. Harwood's Rule 26 report recognizes that the "biomarker" is her key link between generalized allegations of health risk and poultry litter. Without the biomarker, Plaintiffs' health case is pure speculation.¹³

¹³ Plaintiffs' experts all claim a "weight of evidence" approach. *See, e.g.*, Opp. at 17-18. Under *Daubert* such multiple lines of evidence are reviewed individually, as scientific evidence is made no more persuasive or credible simply by being packaged in a so-called "weight of evidence" approach. *See, e.g., Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 144-47 (1997) (affirming exclusion of testimony because "the studies upon which the experts rel[y are] not sufficient, whether individually or in combination, to support their conclusions"); *Allen v. Pa. Eng'g Corp.*, 102 F.3d 194, 196-99 (5th Cir. 1996) ("On examination, none of the scientific data on which appellants' experts rely furnishes a scientifically valid basis for the conclusion they would draw."); *see also, e.g., Truck Ins. Exch. v. MagneTek, Inc.*, 360 F.3d 1206, 1211-13 (10th Cir. 2004) (affirming rejection of plaintiff's "theory as insufficiently reliable to form the basis of expert testimony" because the studies relied upon "all ... cast doubt on the general scientific acceptance, the methodology, and the adequacy of the experimentation underlying [the theory] at this time"); *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 268-70 (2d Cir. 2002)

Second, far from focusing solely on the biomarker, Defendants' Motion demonstrated numerous other shortcomings in Dr. Harwood's allegations of health risk in the IRW. *See* Mot. at 22-25. The sole point to which Plaintiffs respond is the issue of sample hold times, where they admit that nearly three quarters of their bacteria in water data was generated in violation of EPA hold time rules. *See* Opp. at 18; Mot. at 24-25.¹⁴ Indeed, the English study to which Dr. Harwood cites, Mot. Ex. C ¶12, demonstrates that far from being a one-way ratchet in Defendants' favor, Opp. at 18, hold time violations can bias the enumeration either up or down based on prevailing conditions. *See The Effect of Storage on the Coliform and Bacterium Coli Counts of Water Samples*, at 568 (Public Health Laboratory Service Water Sub-Committee 1953) (recognizing that delays in testing can result in both false positives and false negatives, both over- or under-stating bacteria counts).¹⁵ Moreover, even decreases in bacteria counts, Mot. at 18, simply bias the data and invalidate any effort to calculate correlations. Hold time rules should be followed for accurate results. Plaintiffs otherwise have no response to Defendants' demonstration that Dr. Harwood's health risk claims are inconsistent with knowledge regarding the bacteria in question and unsupported by adequate data from the IRW. Mot. at 22-25.

(affirming exclusion of expert testimony because the studies and scientific literature on which plaintiff's experts relied "were not sufficient to support their conclusions").

¹⁴ Plaintiffs' disregard for EPA hold-time rules stands in stark contrast to their dogmatic invocation of EPA's water quality standards as the *sine qua non* for evaluating health risk. Whereas EPA has undertaken to revise the latter, there is no comparable doubt as to the merits of the former. *See* Defendants' Motion to Exclude Expert Testimony Based on Bacterial Analysis Conducted In Violation of EPA, USGS and Oklahoma Standards, Dkt. No. 2090 (May 19, 2009).

¹⁵ Dr. Harwood asserts that "samples were always shipped on ice, and arrived cold at the analytical laboratory." Opp. Ex. C ¶12. Her basis for this testimony is unclear, given that she testified previously to having played essentially no role in Plaintiffs' data collection. *See* Harwood Jan. Depo. at 30:21-31:17, 197:14-25. Moreover, the documentary record suggests otherwise as many samples were not received at the appropriate temperature. *See* Mot. Ex. 14 at 26 (Myoda Rpt.). Plaintiffs' treatment of samples in this case leaves little confidence that their bacteria enumeration shipments were treated any more professionally.

Respectfully submitted,

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I also hereby certify that I served the attached documents by United States Postal Service,
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